

U.S.S.N. 09/785,593

Filed February 16, 2001

REVISED RESPONSE TO RESTRICTION REQUIREMENT

and/or spinal fusion.

Please cancel claims 9 and 10.

Please cancel claims 21-23.

Please cancel claim 32.

DI
BI
Cancel
33. (amended) [A] The resorbable interbody spinal fusion device for spinal fixation of claim
1, [said device comprising 25-100% resorbable material, said device further comprising a
buffering or neutralizing agent] wherein said buffering or neutralizing agent is hydroxyapatite[,
and wherein said device further comprises one or more void spaces therein].

Please cancel claim 34.

Remarks

Claim 1 has been amended to incorporate the limitations of claims 2, 9, and 10. These claims have therefore been cancelled. Claims 32 and 34 have also been cancelled, as have the non-elected claims 21-23.

This application is a continuation of an application which issued as U.S. Patent No. 6,241,771 to Gresser, et al., with the following claims:

1. A substantially wedge shaped resorbable interbody spinal fusion device, wherein said device is substantially manufactured from a resorbable material of poly(d,l-lactide-co-glycolide), said device further comprising a buffering or neutralizing agent wherein said buffering or neutralizing agent is hydroxyapatite, and wherein said device further comprises one or more void spaces therein.
2. A resorbable interbody spinal fusion device, said device shaped substantially as a threaded screw, wherein said device is substantially manufactured from a resorbable material of

U.S.S.N. 09/785,593

Filed February 16, 2001

REVISED RESPONSE TO RESTRICTION REQUIREMENT

poly(d,l-lactide-co-glycolide), said device further comprising a buffering or neutralizing agent wherein said buffering or neutralizing agent is hydroxyapatite, and wherein said device further comprises one or more void spaces therein.

3. A resorbable interbody spinal fusion device for spinal fixation, said device comprising 25-100% resorbable material, wherein said resorbable material is a polymer producing acidic products or low molecular weight resorbable fragments upon hydrolytic degradation, and wherein, further, said resorbable material further comprises a buffering or neutralizing agent in sufficiently high concentration to moderate the rate of change of pH of said resorbable material during resorption, said resorbable material comprises reinforcing fibers and said reinforcing fibers are made of said buffering or neutralizing agent.

4. A resorbable interbody spinal fusion device for spinal fixation, said device comprising 25-100% resorbable material, wherein said device is fabricated from at least two resorbable polymers, and wherein, further, one of said resorbable polymers has been cross-linked in the presence of a crosslinking agent and an initiator, whereby said crosslinked resorbable polymer forms a reinforcing interpenetrating network.

5. The resorbable interbody spinal fusion device of claim 4, wherein said crosslinking agent is vinyl pyrrolidone.

6. The resorbable interbody spinal fusion device of claim 4, wherein said initiator is benzoyl peroxide.

7. A resorbable interbody spinal fusion device for spinal fixation, said device comprising 25-100% resorbable material, wherein said device is fabricated from a polymer wherein molecular chains of said polymer have been aligned to be essentially parallel, and wherein,

U.S.S.N. 09/785,593
Filed February 16, 2001
REVISED RESPONSE TO RESTRICTION REQUIREMENT

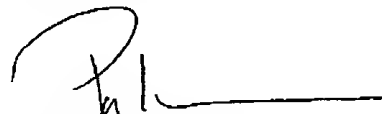
further, said device has been cut such that the aligned polymer molecular chains are at approximately a 45.degree. angle to a surface of said device.

This application was filed to pursue claims to the device, but which will differ in scope, being drawn to specific forms, polymers, and buffering agents.

Applicants elect as the species: (c) threaded screw; (x) hydroxylapatites; and (d) polyester, with the understanding that once the claims to the elected species are determined to be patentable the remaining species will be examined.

Examination on the merits is respectfully requested.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

Date: February 13, 2003
HOLLAND & KNIGHT LLP
2000 One Atlantic Center
1201 West Peachtree Street
Atlanta, Georgia 30309-3400
404-817-8473
404-817-8588 (Fax)

U.S.S.N. 09/785,593
Filed February 16, 2001
REVISED RESPONSE TO RESTRICTION REQUIREMENT

APPENDIX: Claims marked to show Amendments

1. (amended) A resorbable interbody spinal fusion device for spinal fixation, said device comprising 25-100% [resorbable material] polymer producing acidic products or low molecular weight resorbable fragments upon hydrolytic degradation, one or more void spaces, and a buffering or neutralizing agent.

Please cancel claim 2.

3. (amended) The resorbable interbody spinal fusion device of claim [2] 1, wherein one of said one or more void spaces contains a grafting material for facilitating bony development and/or spinal fusion.

4. The resorbable interbody spinal fusion device of claim 3, wherein said grafting material is an autologous grafting material.

5. The resorbable interbody spinal fusion device of claim 1, wherein said device is shaped substantially as a tapered wedge or cone.

6. The resorbable interbody spinal fusion device of claim 1, wherein said device is shaped substantially as a threaded screw.

7. The resorbable interbody spinal fusion device of claim 1, wherein said device is shaped substantially as a threaded rod of cruciform configuration.

8. The resorbable interbody spinal fusion device of claim 5, further comprising at least one serrated or threaded outer face.

Please cancel claims 9 and 10.

11. The resorbable interbody spinal fusion device of claim 1, wherein said resorbable material is a polymer selected from the group consisting of polydioxanone, poly(ϵ -caprolactone), polyanhydride, polyester, copoly(ether-ester), polyamide, polylactone,

U.S.S.N. 09/785,593

Filed February 16, 2001

REVISED RESPONSE TO RESTRICTION REQUIREMENT

poly(propylene fumarate), and combinations thereof.

12. The resorbable interbody spinal fusion device of claim 11, wherein said bioerodible polymer comprises poly(lactide-co-glycolide) with a lactide to glycolide ratio in the range of 0:100% to 100:0% inclusive.

13. The resorbable interbody spinal fusion device of claim 10, wherein said buffering or neutralizing agent is a polymer comprising at least one basic group.

14. The resorbable interbody spinal fusion device of claim 13, wherein said polymer comprising at least one basic group is selected from the group consisting of polyamines, polyesters, vinyl polymers, and copolymers of acrylic acid.

15. The resorbable interbody spinal fusion device of claim 10, wherein said buffering or neutralizing agent is a compound that, on exposure to water, hydrolyzes to form a base.

16. The resorbable interbody spinal fusion device of claim 10, wherein said buffering or neutralizing agent is selected from the group consisting of carbonates, phosphates, acetates, succinates and citrates.

17. The resorbable interbody spinal fusion device of claim 1 wherein said resorbable material further comprises reinforcing fibers.

18. The resorbable interbody spinal fusion device of claim 17, wherein said reinforcing fibers are made of said resorbable material.

19. The resorbable interbody spinal fusion device of claim 10, wherein said resorbable material further comprises reinforcing fibers.

20. The resorbable interbody spinal fusion device of claim 19, wherein said reinforcing fibers are made of said buffering or neutralizing agent.

U.S.S.N. 09/785,593

Filed February 16, 2001

REVISED RESPONSE TO RESTRICTION REQUIREMENT

Please cancel claims 21-23.

24. The resorbable interbody spinal fusion device of claim 10 wherein said buffering or neutralizing agent is selected from the group consisting of compounds wherein the pKa of the conjugate acids of said compounds is greater than the pKa of acids produced by hydrolysis of the polymer(s) from which said device is prepared.
25. The resorbable interbody spinal fusion device of claim 1, wherein said device is fabricated from at least two resorbable polymers.
26. The resorbable interbody spinal fusion device of claim 25, wherein one of said resorbable polymers is poly (propylene fumarate).
27. The resorbable interbody spinal fusion device of claim 25, wherein one of said resorbable polymers has been cross-linked in the presence of a crosslinking agent and an initiator, whereby said crosslinked resorbable polymer forms a reinforcing interpenetrating network.
28. The resorbable interbody spinal fusion device of claim 25, wherein said crosslinking agent is vinyl pyrrolidone.
29. The resorbable interbody spinal fusion device of claim 25, wherein said initiator is benzoyl peroxide.
30. The resorbable interbody spinal fusion device of claim 1, wherein said device is fabricated from a polymer wherein molecular chains of said polymer have been aligned to be essentially parallel.
31. The resorbable interbody spinal fusion device of claim 30, wherein said device has been cut such that the aligned polymer molecular chains are at approximately a 45° angle to a surface

U.S.S.N. 09/785,593

Filed February 16, 2001

REVISED RESPONSE TO RESTRICTION REQUIREMENT

of said device.

Please cancel claim 32.

33. (amended) [A] The resorbable interbody spinal fusion device for spinal fixation of claim
1, [said device comprising 25-100% resorbable material, said device further comprising a
buffering or neutralizing agent] wherein said buffering or neutralizing agent is hydroxyapatite[,
and wherein said device further comprises one or more void spaces therein].

Please cancel claim 34.